IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8971

Bartle, J. November 20, 2012

Diane Boulanger ("Ms. Boulanger" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2001, claimant submitted a completed Green Form to the Trust signed by her attesting physician Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Dr. Evans is no stranger to this litigation. According to the Trust he has signed in excess of 302 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated November 6, 1998, Dr. Evans attested in Part II of Ms. Boulanger's Green Form that she suffered from moderate mitral regurgitation, mitral valve prolapse, and a reduced ejection fraction in the range of 50% to

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2. (...continued)
Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

60%.[3] Based on such findings, claimant would be entitled to Matrix B-1,[4] Level II benefits in the amount of $105,681.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, J.E. Block, M.D., F.A.C.P., stated that claimant had moderate mitral regurgitation. Dr. Block, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In April, 2003, the Trust forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing

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3. Dr. Evans also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

4. In Part I of her Green Form, claimant requested benefits on Matrix A. Upon review of claimant's Green Form and supporting materials, the Trust determined, and claimant did not contest, that Ms. Boulanger was eligible only to receive benefits on Matrix B-1 because claimant's pharmacy records reflected Diet Drug use of less than 61 days. See Settlement Agreement § IV.B.2.d.(2)(b). In addition, the presence of mitral valve prolapse requires the payment of reduced Matrix Benefits. See id. § IV.B.2.d.(2)(c)ii)b).

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because Ms. Boulanger had "mild [mitral regurgitation at] worst."

Based on Dr. Irani's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Boulanger's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant submitted affidavits from Dr. Evans and Gregory R. Boxberger, M.D., F.A.C.C.[7] In his affidavit, Dr. Evans confirmed his previous finding that claimant had moderate mitral regurgitation and stated that claimant's echocardiogram "reveals mitral valve regurgitation of a moderate degree ... with an estimated regurgitant jet area in any apical view between 35-40% of the left atrial area." Dr. Boxberger also concluded that claimant had moderate mitral regurgitation with "an estimated regurgitant jet area in any apical view between 20% and 30% of the left atrial area." Claimant argued, therefore, that she had

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Boulanger's claim.

7. Dr. Boxberger is also no stranger to this litigation. According to the Trust he has signed at least 74 Green Forms on behalf of claimants seeking Matrix Benefits.

established a reasonable medical basis for her claim because two Board-Certified cardiologists agreed that she had moderate mitral regurgitation. In addition, claimant contends that the auditing cardiologist "did not use generally accepted cardiology standards and methodology in arriving at his opinion."

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Irani submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Boulanger had moderate mitral regurgitation. Specifically, Dr. Irani opined that:

> I observed that Claimant's level of mitral regurgitation is visually mild in real time. I also measured the regurgitant jet area in frame number 2:33:23, the frame upon which the Reviewing Physician relies. Accurately measured, Claimant's regurgitant jet area in this frame is 2.61 cm^2. I measured the left atrial area in frame number 2:33:09 and found that it is 17.09 cm^2. When the regurgitant jet area to left atrial area ratio is calculated, the result is 15%, which is clearly mild mitral regurgitation. I did not measure the left atrial area and regurgitant jet area in the same frame because in frame number 2:33:23 the view of the left atrial area is foreshortened and would not be an accurate representation of the size of the left atrial area.

The Trust then issued a final post-audit determination, again denying Ms. Boulanger's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c).

The Trust then applied to the court for issuance of an Order to show cause why Ms. Boulanger's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5245 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 10, 2005, and claimant submitted a sur-reply on November 29, 2005. Under the Audit Rules it is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. Untied States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, claimant reasserts the arguments made in contest; namely, that the opinions of Dr. Evans and Dr. Boxberger provide a reasonable medical basis for finding that claimant had moderate mitral regurgitation. In addition, claimant contends that the concept of inter-reader variability accounts for the difference between the opinions of claimant's physicians and the auditing cardiologist. According to claimant, there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, Ms. Boulanger contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA ratio by an attesting physician is medically reasonable.

In response, the Trust argues that the opinions of claimant's physicians fail to establish a reasonable medical basis for her claim. The Trust notes that Dr. Irani reviewed the specific frames relied upon by claimant's physicians and found that, when measured properly, the level of regurgitation was only mild. In addition, the Trust contends that inter-reader variability does not account for the auditing cardiologist's finding that there was no reasonable medical basis for the claim, as Dr. Irani specifically determined that the "finding of moderate mitral regurgitation was based on a foreshortened view of the left atrial area, which necessarily resulted in exaggeration of [claimant's] true RJA/LAA ratio."

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante noted that:

> Visually, the degree of mitral regurgitation appeared mild in the apical 4-chamber and apical two chamber views. The mitral regurgitation jet was most impressive in the apical two chamber view including the time frames of 2:33:21 through 2:33:23 as stated in the Affidavit of Dr. Boxberger. This view was an apical two chamber view during those time frames. I digitized those cardiac cycles in which the mitral regurgitation appeared most severe in the apical two chamber view including the time frames stated by Dr. Boxberger and Dr. Irani. I then digitally traced and calculated the RJA and LAA. The RJA/LAA ratio was less than 15% on those views in which mitral regurgitation appeared most severe. These calculations

> included the time frames documented by Dr. Boxberger and Dr. Irani. Most of the cardiac cycles demonstrated RJA/LAA ratios of less than 10%. The RJA/LAA ratio never came close to approaching 20%.

After reviewing the entire show cause record, we find claimant's arguments are without merit. First, claimant does not adequately contest the findings of the auditing cardiologist or the Technical Advisor. She does not challenge Dr. Irani's determination that claimant's RJA is 2.61 cm^2 and the LAA is 17.09 cm^2, and that "[w]hen the regurgitant jet area to left atrial area ratio is calculated, the result is 15%, which is clearly mild mitral regurgitation." Nor does she challenge Dr. Vigilante's conclusion that the "RJA/LAA ratio was less than 15% on those views in which mitral regurgitation appeared most severe."[9] Although claimant submitted the affidavits of two cardiologists and argued that Dr. Irani "did not use generally accepted cardiology standards," Ms. Boulanger failed to identify any particular error in the conclusions of the auditing cardiologist or the Technical Advisor. Mere disagreement with the auditing cardiologist or the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

Claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Boulanger had moderate mitral

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9. Despite the opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

regurgitation also is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the Technical Advisor and auditing cardiologist specifically concluded that claimant's echocardiogram demonstrated an RJA/LAA ratio of at most 15%. Adopting claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation by ±15% would allow a claimant to recover Matrix Benefits with an RJA/LAA ratio as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.[10]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Boulanger's claim for Matrix Benefits.

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10. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement that "[a]n echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability."